

B7
Concl

- (X) AAT ATT ACA;
(Y) AAT GGG TCC;
(Z) AAT GCT AGT;
(AA) AAT AAA TCT;
(BB) AAC ATG ACC;
(CC) AAT TAC ACA; or
(DD) AAC ATA ACA. --

REMARKS

Formal examination of this application is respectfully requested.

A human retrovirus has been identified as the causative agent of Acquired Immune Deficiency Syndrome (AIDS). See Barre-Sinoussi et al., Science, 220: 868-871 (1983). A patent describing the retrovirus and a method of detecting antibodies to the virus in human body fluids was recently issued to Dr. Luc Montagnier et al. See U.S. Patent 4,708,818, copy attached. The method involves the use of antigens of the AIDS virus to detect the presence of antibodies in body fluids using a standard immunological reaction. A positive reaction is indicative that the patient contracted the AIDS virus at some point in time. The retrovirus is now known as Human Immunodeficiency Virus (HIV).

The instant application describes and claims DNA sequences corresponding to nucleotide sequences of HIV-1, wherein the claimed DNA sequences are free of viral particles. More particularly, the entire genome of HIV-1 has been cloned, and in the

present application applicants are claiming a number of different DNA sequences corresponding to cloned nucleotide sequences.

The specification has been reviewed for grammatical accuracy and appropriate amendments have been made where required. In addition, typographical errors have been corrected.

The only amendment requiring comment is the revision of page 1, lines 28-31 of the specification to read as follows:

The present invention aims at providing additional new means which are not only useful for the detection of LAV or related viruses, hereafter more generally referred to as "LAV viruses" or "Human Immunodeficiency Virus Type 1" or simply "HIV-1", but also new means that have more versatility, particularly in detecting specific parts of the genomic RNA of said viruses whose expression products are not always directly detectable by immunological methods.

The term "Human Immunodeficiency Virus Type 1" and the abbreviation "HIV-1" were added to this passage of the specification. This term and the abbreviation have also been used in the claims, the title of the invention, and the Abstract. Applicants courteously submit that, for the following reasons, these revisions are fully supported by the specification as originally filed.

The nomenclature used in the claims to describe the virus is the currently recognized, internationally acceptable name for the AIDS retrovirus. More particularly, several isolates of the AIDS retrovirus have been reported by different investigators. The isolates have been referred to in the literature by different designations, such as LAV, IDAVI, IDAV2, HTLV-III, and ARV.

It is now universally recognized that viruses previously denominated by these terms are all variants of the same retrovirus. See, e.g., Nature, 313:636-637 (1985), copy attached.

Moreover, a subcommittee empowered by the International Committee on the Taxonomy of Viruses recently proposed that the AIDS retroviruses be officially designated as the "Human Immunodeficiency Viruses", to be known in abbreviated form as "HIV". A letter with the recommendation of the Subcommittee has been published in Science magazine. A copy of the published letter is attached. Use of this terminology in this application will facilitate the work of future investigators and searchers in locating this pioneering invention.

It is recognized that the designation "Human Immunodeficiency Virus Type 1" and the abbreviation "HIV-1" do not appear in identical form in applicants' specification. Nevertheless, the statute does not require that the language used by applicants to claim their invention appear in *ipsis verbis* in the specification. See In re Lukach, 169 U.S.P.Q. 795, 796 (C.C.P.A. 1971). What the statute does require is that the specification adequately show that the inventors had possession of the invention, as of the filing date of the application relied on, of the specific subject matter later claimed by them. In re Edwards, 196 U.S.P.Q. 465, 467 (C.C.P.A. 1978). Applicants' specification meets this test.

More particularly, applicants used the expression "LAV or related viruses" to refer to the AIDS viruses. Applicants stated that:

LAW OFFICES
FINNEGAN, HENDERSON
FARABOW, GARRETT
8 DUNNER
1775 K STREET, N. W.
WASHINGTON, D. C. 20006
(202) 293-6850

The present invention aims at providing additional new means which should not only also be useful for the detection of LAV or related viruses (hereafter more generally referred to as "LAV viruses"), but also have more versatility, particularly in detecting specific parts of the genomic DNA [sic] of said viruses whose expression products are not always directly detectable by immunological methods.

(Page 1, lines 28-35). While applicants specifically mentioned LAV and related viruses, applicants also taught that their invention extends to variants of the retrovirus:

Needless to say that the invention extends to all variants of genomes and corresponding DNA fragments (ORFs) having substantially equivalent properties, all of said genomes belonging to retroviruses which can be considered as equivalents of LAV.

(Page 17, lines 12-16). The original retrovirus identified as LAV and the variants referred to by applicants in their specification are now known as Human Immunodeficiency Virus Type 1 (HIV-1). Merely claiming the invention using current nomenclature does not alter applicants' invention.

The original claims have been cancelled, and claims 13-57 have been added to the application. In order to assist the Examiner in considering the new claims, the following tabulation lists the new claims and the passages of the application that support the claims.

<u>Claim</u>	<u>Passages of Application</u>
13	Nucleotide positions 236-1759 of the <u>gag</u> gene of HIV-1. Page 9, lines 1-7 Page 16, lines 6-9
14	Nucleotide positions

260-1759 of gag gene.
Page 9, lines 8-12

- 15 Nucleotide coding for p25 protein of HIV-1, free of viral particles.
Page 9, lines 13-16
- 16-30 Nucleotide coding for hydrophilic DNA sequences.
Page 9, lines 17-36
- 31 Pol gene of HIV-1.
Page 10, lines 3-12
- 32-33 Env gene of HIV-1.
Page 10, lines 13-22
- 34-36 Nucleotide coding for peptides with epitopes encoded by env gene.
Page 11, lines 9-28
Page 16, lines 19-24
- 37 Nucleotide coding for preferred DNA sequences (a) through (f) encoded by env gene.
Page 11, line 29 to
Page 12, line 2
- 38-55 Nucleotide coding for preferred hydrophilic DNA sequences encoded by env gene.
Page 12, lines 3-28
- 56-57 Nucleotide coding for preferred peptides comprising epitopic sites encoded by env gene.
Page 11, lines 9-24.

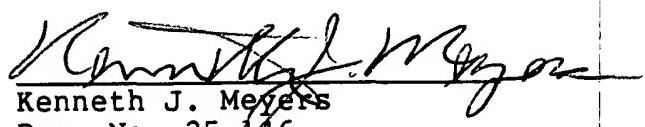
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LAW OFFICES
FINNEGAN, HENDERSON
FARABOW, GARRETT
& DUNNER
1775 K STREET, N.W.
WASHINGTON, D.C. 20006
(202) 293-6850

It is courteously submitted that this application is now in condition for allowance. Favorable action at the Examiner's convenience is courteously solicited.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER

By: 
Kenneth J. Meyers
Reg. No. 25,146

Dated: September 23, 1988

LAW OFFICES
FINNEGAN, HENDERSON
FARABOW, GARRETT
& DUNNER
1775 K STREET, N.W.
WASHINGTON, D.C. 20006
(202) 293-6850